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US DISTRICT COURT
DISTRICT OF MASS.

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA, *ex rel.*
JEFFREY J. BIERMAN,

CASE NO.:

Plaintiff,

v.

COMPLAINT AND
JURY DEMAND

Orthofix International, N.V., Orthologic Corp., dj Orthopedics, Inc., Biomet Orthopedics, Inc., E.B.I., L.P., Bioelectron, Inc., and Smith & Nephew, Inc.

Defendants.

05 - 10557 RCL

MAGISTRATE JUDGE Dein

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INTRODUCTION

Plaintiff/relator, Jeffrey J. Bierman, in the name of and on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Massachusetts, the State of Nevada, the State of Tennessee, the State of Texas, the State of Louisiana, the State of Virginia, and the District of Columbia, by his attorneys, Getnick & Getnick, as and for his complaint, alleges as follows:

1. As more fully alleged herein, this action arises out of a scheme or schemes to defraud the United States of America, certain states, and the District of Columbia perpetrated by the defendants, commencing in or before 1993 and continuing to the date hereof. The defendants make false and fraudulent claims for payment, and make, use or cause to be made or used, false records and statements to get false claims paid to the United States, certain states and the District of Columbia (referred to collectively herein as "the government") for certain items of durable medical equipment ("DME") used by patients in their homes, namely osteogenesis stimulators, covered by Medicare, Medicaid, and other federal and state purchasers of DME. Osteogenesis stimulators use pulsed electromagnetic fields or ultrasound waves to promote bone growth in non-healing fractures. As a result of the submission of these false and fraudulent claims, from 1998 to the present the defendants have received more than $175 million under the Medicare program alone for osteogenesis stimulators and claims for the devices have increased by more than 250%.

2. The allegations in this complaint are made in the present tense because the fraud is ongoing, but apply equally to completed conduct going back to in or before 1993 and continuing to the date hereof.

3. As further set forth in this complaint, the claims are false because the defendants, who manufacture, market, distribute and directly bill for the osteogenesis stimulators, submit claim forms to the government representing: (1) that the devices should be paid as purchase items, when in fact, and to the defendants' knowledge, they should have been billed and paid as rental items; and (2) that the devices were medically indicated and necessary for periods of time that were far in excess of the medical needs of patients, and in the vast majority of cases, the useful lifetime of the devices themselves. The defendants sign express false certifications of such medical necessity when submitting claims to the government.

4. The defendants are the only manufacturers of osteogenesis stimulators in the United States

5. In furtherance of this fraudulent scheme, the defendants, other than Smith & Nephew, Inc., include false information on Certificates of Medical Necessity ("CMNs")[1] and, by misrepresenting regulatory and reimbursement aspects of the devices, cause physicians, their employees and/or clinicians to include false information on CMNs in order to deceive Medicare into paying for the devices as purchase items.

[1] The type of device manufactured by Smith & Nephew, Inc., which uses ultrasound technology, does not require a CMN. These devices have a very small share of the market. See paragraph 44 below.

6. In addition, at least one, and likely all, of the defendants routinely waive the 20% coinsurance that Medicare requires patients to contribute to the cost of covered items and services, a violation of the FCA as well as the Medicare and Medicaid anti-kickback act, 42 U.S.C.1320a-7b(b).

7. Between 1998 and 2003 alone, Medicare purchased more than 40,000 brand new osteogenesis stimulators on behalf of patients. These currently are sitting idle in the homes of those patients, have been thrown out or otherwise disposed of. Osteogenesis stimulators are sold routinely on eBay for as little as $50. Medicare, on the other hand, paid approximately $3,500[2] for each new device, many of which were used by patients for no more than a few months and should have been billed and paid for as rental items at substantially less cost to the government.

8. These acts constitute violations of the federal False Claims Act, 31 U.S.C. § 3729, *et. seq.* ("FCA"), and numerous state equivalent statutes.[3] The FCA provides,

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[2] $3,500 is the approximate cost to Medicare (exclusive of the 20% patient co-payment) of electromagnetic devices reimbursed under E0747 and E0748. Ultrasonic devices reimbursed under E0760 cost around $3,000.

[3] As set forth below, the defendants' acts constitute violations of the California False Claims Act, Cal. Gov't Code §§ 12650-12655; the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081-092; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1-8; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-182 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 et seq.; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§ 1-1188.13-19; the Delaware False Claims and Reporting Act, 6 Del. C. § 1201(a)(1); the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(1); the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46:438.3(A); the Massachusetts False Claims Act, Mass. Gen. L. Ch. 12, §§ 5B(1); the Nevada False

inter alia, that any person who knowingly presents and/or causes to be presented to the United States a false or fraudulent claim for payment, or who knowingly makes, uses or causes to be made or used, a false statement to get a false or fraudulent claim paid, is liable for a civil penalty of up to $11,000 for each claim, plus three times the amount of the damages sustained by the Government. The FCA allows any person discovering a fraud perpetrated against the Government to bring an action for himself and for the Government and to share in any recovery. The complaint in an FCA action is filed under seal for 60 days (without service on the Defendant within such 60-day period) to enable the Government (1) to conduct its own investigation without the defendant's knowledge and (2) to determine whether to join in the action.

9. The plaintiff/relator, Jeffrey J. Bierman, ("the relator") is the co-owner of a 25-person company located in Missouri that provides surgical and DME non-coding medical billing services and compliance programs to doctors, hospitals, nursing homes and other health care providers. 40% of the relator's business relates to DME. In 2001, the relator's company was recognized by the Health Care Financing Administration (now known as the Centers for Medicare and Medicaid Services ("CMS")) as a Gold Star Preferred Billing Service.

10. The relator seeks to recover treble damages and civil penalties in the name of the United States for the violations alleged herein, amounting to hundreds of millions of dollars.

Claims Act, Nev. Rev. Stat. § 357.040(1)(a); and the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1)

JURISDICTION AND VENUE

11. This court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367 and 31 U.S.C. § 3732.

12. Personal jurisdiction is proper in this district pursuant to 31 U.S.C. §3732(a) since at least one of the defendants transacts business in this district, and/or at least one violation of 31 U.S.C. §3729 occurred in this district, and pursuant to a constitutional minimum contacts analysis. Venue is proper in this district pursuant to 31 U.S.C. §3732(a) since at least one of the defendants transacts business in this district and/or at least one violation of 31 U.S.C. §3729 occurred in this district Venue also is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 31 U.S.C. § 3732(a), since at least one of the defendants resides and/or may be found in this district.

PARTIES

13. The relator is a citizen of the United States and a resident of the state of Missouri. The relator became aware of the fraudulent scheme alleged in this action in the course of his business as a provider of DME billing services to health care providers. He is an original source within 31 U.S.C. § 3730(e)(4).

14. Defendant Orthofix International N.V. ("Orthofix") is a publicly-traded company incorporated in Curacao, Netherlands Antilles. Orthofix is located in the United States at 1720 Bray Central Drive, McKinney, TX 75069. Orthofix manufactures,

markets and distributes a broad range of minimally invasive surgical and non-surgical products for orthopedic applications. Amongst other products, Orthofix manufactures, markets, distributes and directly bills Medicare for the Spinal Stim and Physio-Stim osteogenesis stimulators. In 2005 Orthofix received FDA approval for and began marketing the Cervical-Stim osteogenesis stimulator for use in the cervical (upper) spine. As of September 30, 2004, Orthofix International N.V. had $429.6 million of total assets. Net income for the first nine months of 2004 was $24.6 million, an increase of 37% over the previous year. Orthofix has an excellent capital base and is extremely profitable.

15. Defendant Orthologic Corp. ("Orthologic") is a publicly-traded company located at 1275 West Washington St., Tempe, AZ 85281. Orthologic describes itself as a "pure-play orthobiologics drug development company." Prior to November 2003, Orthologic manufactured, marketed, distributed and directly billed Medicare for bone growth stimulation devices, including the SpinaLogic osteogenesis stimulator. On November 26, 2003 Orthologic sold all of its revenue producing operations to defendant dj Orthopedics, Inc. for $93 million in cash and the assumption of substantially all of the trade payables and other current liabilities related to those operations. As of September 30, 2004, Orthologic had cash reserves of approximately $109.4 million and total liabilities of $4.7 million with no debt.

16. Defendant dj Orthopedics, Inc. ("dj Orthopedics") is a publicly-traded company located at Vista, CA. dj Orthopedics is a global sports medicine company

specializing in rehabilitation and regeneration products for the non-operative orthopedic and spine markets. In November 2003 dj Orthopedics purchased the bone growth stimulation business of Orthologic, including the OL1000 Bone Growth Stimulator and the SpinaLogic osteogenesis stimulator. These devices are manufactured and marketed by the Regentek division of dj Orthopedics, which directly bills Medicare for the devices. As of September 30, 2004, dj Orthopedics had $317.3 million of total assets. Net income for the first nine months of 2004 was $8.7 million, an increase over the previous year of 8%. dj Orthopedics, Inc. has an excellent capital base and is profitable.

17. Defendant Biomet Orthopedics, Inc. ("Biomet") is the fifth largest producer of orthopedic products worldwide. Biomet is a publicly traded company located at 56 Bell Drive, Warsaw, Indiana 46581. As of May 31, 2004, Biomet had $1.8 billion of total assets. Net income for the year ended May 31, 2004 was $325.6 million, an increase over the previous year of 13.6%. Biomet has an excellent capital base and is extremely profitable.

18. Defendant EBI, L.P. ("EBI") is a wholly owned subsidiary of Biomet and is located at 100 Interpace Parkway, Parsippany, New Jersey 07054. EBI designs, manufactures, markets, distributes and directly bills Medicare for the SpinalPak and OrthoPak osteogenesis stimulators and other products used by orthopedic medical specialists in surgical and non-surgical therapy.

19. Defendant Bioelectron, Inc., ("Bioelectron") was purchased by EBI in September 2000 and is a wholly owned subsidiary of EBI. As a result of the acquisition of Bioelectron, EBI added to its product line the SpinalPak and the OrthoPak osteogenesis stimulators.

20. Defendants Biomet, EBI and Bioelectron are referred to in this complaint collectively as "Biomet/EBI."

21. Defendant Smith & Nephew plc is a global medical devices company that manufactures the Exogen Bone Healing System, an ultrasound osteogenesis stimulator. Smith & Nephew plc is based in the UK where it is publicly traded. In the United States, Smith & Nephew, Inc. ("Smith & Nephew") is located at 1450 E. Brooks Road, Memphis, TN 38116. Amongst numerous other products, Smith & Nephew manufactures, markets, distributes and directly bills Medicare for the Exogen Bone Healing System, an osteogenesis stimulator that transmits a low intensity ultrasound signal to the fracture site through coupling gel. Smith & Nephew plc has over 8,000 employees and operates in 32 countries around the world generating annual sales of nearly 1.2 billion pounds sterling.

SUMMARY OF FRAUDULENT SCHEME

22. Non-invasive osteogenesis (bone growth) stimulators are light weight, battery operated devices worn externally by patients with non-healing bone fractures for a

few hours each day. They are designed to promote bone growth and healing by inducing weak electromagnetic fields or ultrasonic waves in the bone. They were approved by the FDA in 1979 and are covered by Medicare for non-healing fractures and as an adjunct to spinal surgery under three HCPCS codes, E0747 (electromagnetic, long bone), E0748 (electromagnetic, spinal) and E0760 (ultrasonic). (See further, paragraphs 40-42 below.)

23. The length of use required to achieve bone healing varies from patient to patient. According to clinical studies (see paragraphs 56-59 below), most patients use the devices for periods of between 3 and 6 months. The physician monitors the patient's progress from the commencement of therapy and determines when either bone healing has occurred or the device appears to have failed. In either event, its use is then discontinued. Two of the defendants, Orthofix and Smith & Nephew, offer a money-back guarantee if their devices do not achieve bone healing within 6 months.

24. The electromagnetic devices manufactured by defendants Orthofix, dj Orthopedics and Biomet/EBI (and previously manufactured by Orthologic) contain a computer chip that is programmed to cause the device to automatically deactivate after 9 months of regular use. The ultrasonic device manufactured by defendant Smith & Nephew does not have this deactivation feature. As set forth above, the Smith & Nephew device has a very small share of the market.

25. The clinical reasons for this deactivation feature have not been explained by the manufacturers. In FDA filings the manufacturers state that, while the long term effects of exposure to electromagnetic fields are not known, no adverse affects on health have been identified. The initial Premarket Approval Application for noninvasive osteogenesis stimulators submitted by defendant Biomet/EBI and approved by the FDA in 1979 states: "Routine clinical observations over 5 years indicate this device causes no known risks."

26. Medicare pays for osteogenesis stimulators on a monthly rental or purchase basis according to a fee schedule. Medicare will pay for monthly rental up to the fee schedule purchase price, at which point the rental payments stop. While the fee schedule varies state by state, the purchase price consistently is approximately 10 times more than the rental price (see paragraph 43 below). Therefore, a device would have to be used for a period of 10 months or more for the accrued rental payments to reach the purchase price. However, since the devices typically are used for periods of between 3 and 6 months, and because the E0747 and E0748 devices deactivate after 9 months, the monthly rental charges would never reach the purchase price. In many, possibly most, cases the monthly rental payments for the actual time used would be considerably less than the purchase price.

27. The defendants nonetheless routinely bill the devices to Medicare and others as purchase items. The defendants claim and receive from Medicare approximately

$3,500[4] up front for each osteogenesis stimulator prescribed and have collected more than $175 million under the Medicare program since 1998. As set forth above, each of the manufacturers has its own billing personnel who directly bill Medicare, other insurers and patients. Only a handful of third party suppliers have been permitted to purchase the devices. These Medicare revenues therefore have for the most part accrued directly to the defendants.

28. Medicare requires that a CMN be filed with each claim under E0747 and E0748. A CMN is not required for claims under E0760. The allegations in paragraphs 29 – 32 and 36 – 38 below do not apply to the manufacturer of the E0760 device, Smith & Nephew.

29. The defendants who manufacture the E0747 and E0748 devices, Orthofix, Biomet/EBI, Orthologic and dj Orthopedics, mislead physicians and their clerical staff into filling out CMNs containing a code indicating that the devices are medically necessary for the patient's lifetime or for periods of time that exceed the devices' 9 months of useful life, as set forth in paragraphs 30 – 39 below. Other evidence suggests that the defendants may even by-pass physicians altogether and simply make some or all of the medical necessity certifications themselves, contrary to Medicare rules and federal laws. (See below, paragraph 66.)

[4] See footnote 2 above.

30. The CMN requires the physician to state how long he/she expects the patient will need to use the device. The CMN gives the physician the option of specifying a number of months or entering the code "99," indicating that the patient will need the device for life. (See paragraph 55 below.)

31. In the vast majority of cases, the "medical necessity" section of the CMN is completed by the physician's clerical assistant and the CMN is signed off by the physician. These clerical assistants typically rely on the equipment suppliers' representatives for advice about how the CMN should be completed in order to ensure that claims will be processed and paid by Medicare and other insurers. Equipment suppliers are permitted or required, under Medicare rules, to complete some sections of the CMN (although not the "medical necessity" section) and routinely do so. (See paragraph 53 – 54 below.)

32. In order to mislead physicians and their clerical staff into filling out CMNs supporting the defendants' claims for payment for the devices as purchase items, the defendants routinely instruct them to include the code "99" on the CMN or otherwise specify a number of months that will support payment for the item as a purchase. The defendants routinely claim that the devices have been designated by the FDA as devices that are disposable and can only be used by one patient. Citing the fact that the devices deactivate after a period of months, the defendants routinely claim that the devices "cannot" be reused and must be billed as a purchase, apparently on the basis that the concept of a single-use device is

incompatible with rental. For example, a representative of defendant Orthofix told the relator, who pointed out that Medicare had assigned a rental code to the devices, that "nobody honors" it. (See paragraph 72 below.)

33. Medical devices that can only be used by one patient are referred to in FDA parlance as "Single Use Devices" ("SUDs"). SUD designation is not an FDA requirement but is applied at the discretion of the device manufacturer. Further, many SUDs can be and are in fact reprocessed, subject to compliance with FDA reprocessing rules.

34. It is well-recognized in the health care profession that SUDs frequently are misdesignated as such by manufacturers in order to boost profits. In a June 2000 report on the reprocessing of SUDs, the GAO observed:

> "Many health care professionals believe that some SUDs can be reused. They told us they distrust the single-use label for some devices because (1) FDA cannot require manufacturers to support the designation of a device as single-use; (2) they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable; and (3) FDA's approval requirements for SUDs are less extensive than those for reusable devices ...
>
> On occasion, manufacturers have contributed to the sense that compliance with the single-use label is not always necessary . . . [For example,] a major manufacturer of pulse oximeter sensors, essentially offer[s] to sell 'remanufactured' sensors for reduced prices to health care institutions that return their used single-use sensors to the company . . . ." (emphasis added)

35. In fact, the alleged single-use designation for osteogenesis stimulators is economically and not clinically motivated. The patient safety reasons, if any, for

limiting use to a single patient are obscure and have not been explained by the manufacturers. The devices are non-sterile, they are worn externally, often over clothing, and any electrodes intended to be attached to the skin are disposable. As set forth above (paragraph 25), the clinical rationale for the deactivation feature likewise has not been explained by the manufacturers. In fact, this feature serves no other purpose than to prevent re-use. (See paragraph 36 below.)

36. A 1993 newspaper article reported on the efforts of one patient to give his Orthopak bone growth stimulator to another user when the patient's bone gap healed after 4 months. His doctor replied that "the FDA wouldn't allow it to be used on more than one patient." His doctor also noted that "the logic behind the one-use rule eludes him. It's not as though the device gets contaminated while in use." The article continues:

> "Ron McNeill, sales and marketing director for Bioelectron, said the company doesn't plan to ask the FDA to allow multiple-patient use for two reasons: It is concerned about inappropriate use, and it would lose its profit margin.
>
> 'We think we're already saving an individual money,' McNeill said.
>
> To prevent reuse, he said, the company installs a computer chip that automatically shuts the device down after 200 days of use, or a total of 4,800 hours."

Carol Gentry, "Useful Device Sits on Shelf," *St. Petersburg Times*, November 29, 1993, p. B1. (emphasis added)

37. Further, like the manufacturer of pulse oximeter sensors referred to in the GAO's report referenced above, at least one defendant admits that its osteogenesis stimulators can be, and are in fact, reprocessed. As further set forth in paragraph

70 below, a Biomet/EBI representative stated in 2003 that Biomet/EBI will take used devices back, refurbish them and give them to indigents.

38. The alleged single-use device designation thus is no more than a ploy to mislead physicians and their staff into believing that Medicare will not process payment for the devices unless they are billed as a purchase, and to cause physicians and their staff to include false information on CMNs supporting the manufacturers' claims for the devices as a purchase.

39. Whether or not osteogenesis stimulators are designated as single-use devices, they should never be billed to Medicare as a purchase and should always be billed as a rental. This is because: (a) Medicare has designated osteogenesis stimulators as rental OR purchase items; (b) the period of medical necessity will never be known in advance of treatment, but will be determined in the course of treatment by the physician on the basis of x-rays of the patient's progress (and so billing should occur on a month-to-month basis); (c) Medicare will pay for the devices on a rental basis for as long as the devices are medically necessary, up to the cost of the purchase price; (c) clinical studies show that patients use the devices for approximately 3 to 6 months; (d) as to E0747 and E0748 devices, the period of medical necessity for a single device could never exceed 9 months (since the devices are programmed to deactivate after 9 months); and (e) the purchase price is equal to 10 months of rental, one month more than the useful life of the E0747 and E0748 devices, and four months longer than the usual maximum period of use for all devices.

MEDICARE REIMBURSEMENT FOR OSTEOGENESIS STIMULATORS

40. Medicare coverage for noninvasive electrical stimulation for fracture healing has been in effect since September 15, 1980. Initial coverage was limited to nonunion of long bone fractures, failed fusion and congenital pseudarthroses. In 1996 coverage was expanded to include the use of both non-invasive and invasive osteogenic stimulation as an adjunct to spinal fusion surgery. In 2001 coverage was again expanded to include osteogenesis stimulation using ultrasound (as distinct from electromagnetic currents) for the treatment of non-union fractures.

HCPCS Codes and Coverage Criteria

41. Suppliers making claims for reimbursement for DME identify the items on claim forms using unique codes, known as HCPCS codes. Osteogenesis stimulators are reimbursed by Medicare under the HCPCS codes EO747, EO748 and EO760, as follows:

    a. EO747: Osteogenesis stimulator, electrical, non-invasive, other than spinal applications.

    b. EO748: Osteogenesis stimulator, electrical, non-invasive, spinal applications.

    c. EO760: Osteogenesis stimulator, low intensity ultrasound, non-invasive.

42. Medicare coverage criteria for osteogenesis stimulators are as follows:

a. EO747:

i. Nonunion of a long bone fracture where fracture healing has ceased for more than three months[5] prior to starting treatment.

ii. Failed fusion of a non spinal joint where a minimum of nine months has elapsed since the last surgery.

iii. Congenital pseaudoarthrosis.

b. EO748

i. Failed spinal fusion where a minimum of nine months has elapsed since the last surgery.

ii. Following a multilevel spinal fusion surgery.

iii. Following a spinal fusion surgery where there is s history of a previously failed spinal fusion at the same site.

c. EO760 (ultrasound)

i. Nonunion of a fracture, and documented failure of at least one open surgical intervention for treatment of the facture.

ii. The fracture cannot be of the skull or vertebrae or tumor-related.

See: Medicare Coverage Issues Manual, Section 35-48.

[5] Prior to 2000, an E0747 device was covered for nonunion of a long bone fracture where fracture healing has ceased for more than nine months prior to starting treatment. This coverage change was made after intensive lobbying by Orthofix and Biomet/EBI.

Medicare Fee Schedule

43. Osteogenesis stimulators are reimbursed by Medicare on either a purchase or monthly rental basis. While the Medicare fee schedule payments vary slightly from one state to another, the purchase price consistently is approximately 10 times more than the rental price. For example, the fee schedule purchase price for an E0747 device in Maryland (DMERC Region B) is $3,407.65 and the rental price is $340.74. The purchase price for an E0748 device in Massachusetts (DMERC Region A) is $3,696.01 and the rental price is $369.60. The purchase price for an E0760 device in California (DMERC Region D) is $2973.20 and the rental price is $297.33. Nationwide, the approximate purchase price of devices reimbursed under E0747 and E0748 is $3,500 and the approximate rental price is $350. The approximate purchase price of E0760 devices is approximately $3,000 and the rental price approximately $300.

Medicare Reimbursements from 1998 to 2003

44. As further set forth in this complaint, osteogenesis stimulators have been billed almost without exception as purchase items. Medicare reimbursements between 1998 and 2003 (the years for which data is currently available to the relator) exceed $133 million. In 2000, 2001, 2002 and 2003, E0747 and E0748 were in the top 200 Level II HCPCS Codes, ranked according to total annual reimbursements. Reimbursements under E0747 grew by 251% between 1998 and

2003. Reimbursements under E0748 grew by an extraordinary 308% during those years.

	Code: E0747 (not spinal)		**Code: E0748 (spinal)**		**Code: E0760 (ultra sound)**	
Year	Charges	No. of devices	Charges	No. of Devices	Charges	No. of devices
2003	$17,166,052	5,085	$25,520,001	7,290	not in top 200	not in top 200
2002	$13,074,171	3,888	$19,923,083	5,724	not in top 200	not in top 200
2001	$9,412,826	2,832	$13,594,422	3,919	not in top 200	not in top 200
2000	$8,769,299	2,738	$11,232,505	3,361	not covered	not covered
1999	not in top 200	not in top 200	$7,897,115	2,364	not covered	not covered
1998	$6,427,197	2,024	not in top 200	not in top 200	not covered	not covered
TOTAL	$54,849,545	16,567	$78,167,126	22,658	NA	NA

Source: http://www.cms.hhs.gov/statistics/feeforservice

Medicare Reimbursement Rules

45. Reimbursement for DME, prosthetics, orthotics and supplies ("DMEPOS") is established by Medicare fee schedules. The fee schedule classifies most DMEPOS into one of six categories (42 U.S.C. §1395m (a)):

    a. Inexpensive or other routinely purchased;

    b. Items requiring frequent and substantial servicing;

c. Customized items;

d. Other prosthetic and orthotic devices;

e. Capped rental items;

f. Oxygen and oxygen equipment

46. Osteogenesis stimulators are classified in the "inexpensive or other routinely purchased" category, also known as Category 1. Payment for inexpensive and routinely purchased items is made on a monthly rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount. (42 C.F.R. §414.220(b)(1).) The total amount of payments made for an item cannot exceed the purchase price stated in the fee schedule. (42 C.F.R. §414.220(b)(3).) Medicare will pay for monthly rental up to the fee schedule purchase price, at which point the rental payments stop. See, e.g., Region B DMERC Supplier Manual, Chapter 14 – Payment Policy, page 11 of Revision 32, December 2002.

47. All claims for reimbursement must be justified by medical need. (42 U.S.C. 1395y(a)(1)(A): "No payment may be made under Part A or Part B for any expenses incurred for items or services … which are not reasonable or necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member").

Procedure for Making Claims

48. In order to make a claim for payment under E0747 and E0748, the supplier must submit to CMS a Health Insurance Claim Form, FORM CMS-1500 ("1500 Form") and a Certificate of Medical Necessity FORM DMERC 04.03C ("CMN"). The procedure is the same under E0760 except that no CMN is required.

The 1500 Form

49. When completing the 1500 Form, the supplier is required to indicate by the use of a "modifier" whether the item is being billed as a rental item (signified by the modifier RR), a purchase of new equipment (signified by the modifier NU) or a purchase of used equipment (signified by the modifier UE). (See, e.g., DMERC Region D Supplier Manual, Chapter 5.) The modifier appears immediately after the HCPCS code in Box 24D of the 1500 Form.

50. The supplier also must include the charge for the items or services in Box 24F of the 1500 Form.

51. When submitting the 1500 Form, the supplier is required to make an express written certification that "the services shown on the form were medically indicated and necessary to the health of the patient."

The CMN

52. The CMN must be signed by the ordering physician, a physician employee, or a non-physician clinician (such as a home health nurse or physical therapist). This signature appears in Section D of the CMN and attests *inter alia* that the medical necessity information in the CMN is true, accurate and complete.

53. Section C of the CMN is headed: "Narrative Description of the Equipment and Cost." This section must be completed by the supplier and include a description of the item, the supplier's charge and the Medicare Fee Schedule Allowance for the item.

54. Section B of the CMN is headed: "Information in this Section May Not Be Completed by the Supplier of the Items/Supplies." Section B contains "medical necessity" information and must be completed by the ordering physician, a physician employee, or a non-physician clinician (such as a home health nurse or physical therapist). 42 U.S.C. 1395m(j)(2)(A) provides civil money penalties for distributing to physicians and/or beneficiaries CMNs containing information other than the identification of the supplier and beneficiary and the description, product code, fee schedule amount and supplier's charge for the equipment.

55. Section B provides for the physician, physician employee or clinician to indicate the length of time the physician expects the patient to require use of the ordered